

CLAIMS

We Claim:

1. A method for treating a human patient afflicted with cancer, comprising administering therapeutically effective amounts of temozolomide and pegylated interferon alpha to such a patient.

2. The method of claim 1, wherein the temozolomide is administered in repeated cycles, each cycle having a dosing period in which the temozolomide is administered daily at a dose of 50 to 400 mg/m<sup>2</sup>/day for 5 to 25 days, followed by a rest period of 5 to 14 days in which temozolomide is not administered.

10 3. The method of claim 2, wherein the pegylated interferon alpha is pegylated interferon alpha-2b, and is administered in an amount of from 1.0 to 9.0 micrograms per kilogram administered once a week.

15 4. The method of claim 3, wherein the pegylated interferon alpha-2b is administered in an amount of from 1.0 to 6.5 micrograms per kilogram administered once a week.

5. The method of claim 4, wherein the pegylated interferon alpha-2b is PEG<sub>12000</sub>-interferon alpha.

20 6. The method of claim 1, wherein the temozolomide is administered in repeated cycles, each cycle having a dosing period in which the temozolomide is administered daily at a dose of 100 to 200 mg/m<sup>2</sup>/day for 5 to 25 days, followed by a rest period of 5 to 14 days in which temozolomide is not administered.

7. The method of claim 6, wherein the temozolomide dosing period is one or three weeks, and the temozolomide rest period is one week.

25 8. The method of claim 7, wherein the pegylated interferon alpha is pegylated interferon alpha-2b, and is administered in an amount of from 1.0 to 9.0 micrograms per kilogram administered once a week.

9. The method of claim 8, wherein the pegylated interferon alpha-2b is PEG<sub>12000</sub>-interferon alpha.

10. The method of claim 9, wherein the pegylated interferon alpha-2b is administered in an amount of from 1.0 to 6.5 micrograms per kilogram administered once a week.

11. The method of claim 2, wherein the pegylated interferon alpha is pegylated interferon alpha-2a, and is administered in an amount of from 50 to 500 micrograms once a week.

12. The method of claim 11, wherein the pegylated interferon alpha-2a is administered in an amount of from 200 to 250 micrograms once a week.

13. The method of claim 1, wherein the temozolomide is administered in repeated cycles, each cycle having a dosing period in which the temozolomide is administered daily at a dose of 100 to 200 mg/m<sup>2</sup>/day for 5 to 25 days, followed by a rest period of 5 to 14 days in which temozolomide is not administered, and wherein the pegylated interferon alpha is pegylated interferon alpha-2a, and the pegylated interferon alpha-2a is administered in an amount of from 50 to 500 micrograms once a week.

14. The method of claim 13, wherein the temozolomide dosing period is one or three weeks, and the temozolomide rest period is one week.

15. The method of claim 1, wherein the temozolomide is administered daily for six weeks at a dose of 50 to 200 mg/m<sup>2</sup>/day, and wherein the pegylated interferon alpha is pegylated interferon alpha-2b, and the pegylated interferon alpha-2b is administered in an amount of from 1.0 to 9.0 micrograms per kilogram administered once a week.

16. The method of claim 15, wherein the pegylated interferon alpha-2b is PEG<sub>12000</sub>-interferon alpha.

17. The method of claim 16, wherein the pegylated interferon alpha-2b, is administered in an amount of from 1.0 to 6.5 micrograms per kilogram administered once a week.

18. The method of claim 1, wherein the temozolomide is administered daily for six weeks at a dose of 50 to 200 mg/m<sup>2</sup>/day, and wherein the pegylated

interferon alpha is pegylated interferon alpha-2a, and the pegylated interferon alpha-2a is administered in an amount of from 50 to 500 micrograms once a week.

19. The method of claim 1, wherein the temozolomide and pegylated interferon alpha are administered in repeated 28 day cycles, each 28 day cycle having a dosing period wherein the temozolomide is administered on days 1-7 and 15-21 of said cycle at a daily dose of 75 to 150 mg/m<sup>2</sup>/day and wherein the pegylated interferon alpha is administered on days 1, 8, 15 and 22 at a daily dosing of 1.5 to 6.0 micrograms per kg per day.

10 20. The method of claim 19, wherein the pegylated interferon alpha is pegylated interferon alpha-2b.

15 21. The method of claim 19, wherein the pegylated interferon alpha-2b is PEG<sub>12000</sub>-interferon alpha.

22. A medical kit for treating a cancer patient is provided, comprising:

- 15  
(a) a supply of temozolomide;  
(b) a supply of pegylated interferon alpha; and  
(c) printed instructions for administering temozolomide and pegylated interferon alpha to a cancer patient.